

## 510(k) Summary

**Date Prepared:** December 23, 2011

### Submitter's Name / Contact Person

<u>Submitter</u>	<u>Contact Person</u>
Waters Medical Systems, LLC	Robert Warren
2112 - 15th Street NW	Phone: 507-288-7777
Rochester, Minnesota 55901	Email: <a href="mailto:bobw@wtrs.com">bobw@wtrs.com</a>

### General Information

Trade Name	WAVES
Common / Usual Name	Renal Preservation System
Classification Information	21 CFR 876.5880 (Class II) Isolated kidney perfusion and transport system and accessories
Predicate Devices	RM3 Renal Preservation System, Waters Medical Systems, LLC Lifeport Kidney Perfusion Transporter, Organ Recovery Systems Inc.

### Device Description

The WAVES is a transportable, self-contained renal preservation system, designed to support static monitoring and transportation of kidneys. The WAVES system provides controlled pulsatile kidney perfusion using oxygenated hypothermic physiologic solutions, and monitors, displays, trends, and saves important perfusion parameters, including: perfusate flow, temperature, pressure, and renal resistance. The WAVES system can be configured to signal an audio and visual alarm for user-selected limits.

The WAVES is a two-part system comprising a 'control unit' for perfusion and monitoring of a single kidney, and a sterile, single-use, disposable 'cassette module' used to contain, refrigerate, and circulate perfusate to and through the kidney.

### Intended Use / Indications

The WAVES is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for preservation, transportation, and eventual transplantation into a recipient.

### Substantial Equivalence and Summary of Studies

The WAVES device is substantially equivalent to the RM3 Renal Preservation System and the Lifeport Kidney Perfusion Transporter. All systems have substantially equivalent intended use and principle of operation. The subject and the two predicate devices are intended to maintain kidneys for transplantation by providing hypothermic physiologic perfusion using a single use, disposable cassette module and perfusion circuit.

The perfusion control for the WAVES and the predicates is substantially equivalent. The WAVES perfusion control includes the perfusate control parameters, the perfusate pressure, the automatic features operated through the user interface and the cassette priming. The perfusion control of the WAVES has been evaluated through a pump performance testing and a software validation testing.

The hypothermic control for the WAVES and the predicates is substantially equivalent. The WAVES hypothermic control includes the cassette mounting, the cooling method, the cooling duration and temperature and the heat exchanger. The hypothermic control of the WAVES has been evaluated through a cooling system performance testing and a software validation testing.

The WAVES disposable cassette module is provided sterile and labeled with an expiration date as the RM3 disposable cassette. The sterilization cycle for the WAVES system has been validated in accordance with ISO 11135-1 requirements. The labeled shelf life of the WAVES cassette is supported through accelerated aging testing.

Differences between the WAVES and the predicates are related to the user interface and biomaterials used to construct the disposable cassette module. The software validation testing results have shown the user interface operates as expected. ISO 10993 compliant biomaterial testing has demonstrated that the new biomaterials are safe for their intended biocontact.

Results of evaluations did not raise any new questions of safety or effectiveness when compared to the predicate devices and therefore the WAVES is substantially equivalent to the RM3 and the Lifeport predicates.

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## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Robert Warren  
General Manager  
Waters Medical Systems, LLC  
2112 - 15th Street NW  
ROCHESTER MN 55901

FEB 16 2012

Re: K111521

Trade/Device Name: WAVES

Regulation Number: 21 CFR§ 876.5880

Regulation Name: Isolated kidney perfusion and transport system and accessories

Regulatory Class: II

Product Code: KDN

Dated: January 27, 2012

Received: January 30, 2012

Dear Mr. Warren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

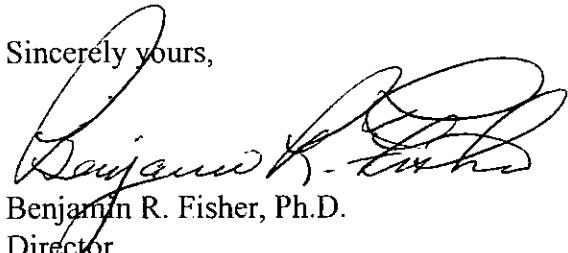
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): **K111521**

Device Name: **WAVES**

#### Indications for Use:

The WAVES is intended to be used for the pulsatile hypothermic machine perfusion of kidneys for preservation, transportation, and eventual transplantation into a recipient.

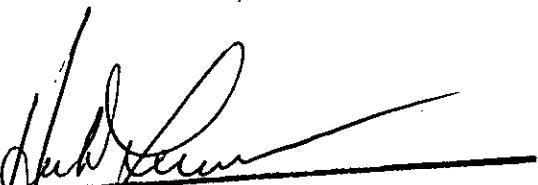
Prescription Use  \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

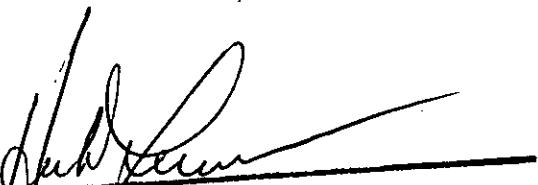
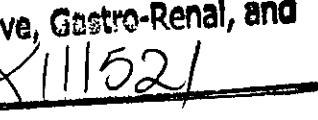
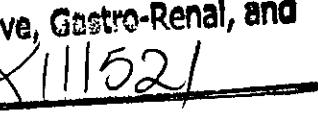
AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Reproductive, Gastro-Renal, and  
Urological Devices   
510(k) Number   
**K111521**